Message

**From**: John E. Morrone [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A2B2444E7EC948AEABC7ACD4F01F3D0B-JOHN E. MOR]
**Sent**: 8/20/2020 7:12:44 PM
**To**: Charles Boyd [CharlesB@Safechain.com]
**CC**: Martha M. Rumore [mrumore@frierlevitt.com]; Donna Halpin [DHalpin@frierlevitt.com]
**Subject**: Recall Memorandum Wholesaler 4821-9072-7880 v.1
**Attachments**: Recall Memorandum Wholesaler 4821-9072-7880 v.1.pdf

Charlie,

Here is the memo regarding the recall.

Very truly yours,

John E. Morrone, Esq.
Partner

FRIER LEVITT
ATTORNEYS AT LAW

101 Greenwich Street
Suite 8B
New York, NY 10006
**direct: (646) 970-4017**
phone: (646) 970-2711
fax: (973) 618-0650
email: jmorrone@frierlevitt.com
web: www.frierlevitt.com

*Pine Brook Office*
84 Bloomfield Avenue
Pine Brook, NJ 07058






FL00018080

FRIER LEVITT
ATTORNEYS AT LAW

Martha M. Rumore, Pharm.D., Esq.
direct: 646.970.3226
mrumore@frierlevitt.com

MEMORANDUM

TO: SafeChain Solutions

FROM: Martha M. Rumore, PharmD, Esq.

DATE: August 20, 2020

RE: Drug Recall Wholesaler Procedures- SafeChain

---

Pharmaceutical Recalls Procedures follow 21 CFR Part 7 Subpart C as well as Chapter 7 of the FDA Regulatory Procedures Manual.[1] Guidelines for industry are specifically located at 21 CFR 7.40-7.59. In March 2020, FDA issued a Guidance for Industry for Product Recalls.[2] Recalls for pharmaceuticals are either voluntarily initiated by the manufacturer or "requested" by the FDA (the incentive being that seizure, injunction or criminal prosecution may follow for failure to heed FDA's "request."). FDA classifies, monitors and assesses the effectiveness of recalls via audit. The manufacturer in conjunction with the FDA develops a recall strategy which FDA reviews and may suggest changes including a public announcement. FDA also determines when a recall is completed.

Several assumptions have been made regarding the business entity model of SafeChain in the preparation of this memorandum. The first is that SafeChain is a wholesaler or a wholesaler-distributer, not a manufacturer or retailer. The second assumption is that based on the nature of the recall, pursuant to FDA's Health Hazard Evaluation, this will most likely be a Class I or II recall to the Retail Level.[3,4] However, many factors enter into FDA's decision including a Market Assessment which takes into

---

[1] FDA, Regulatory Procedures Manual, Chapter 7, Recall Procedures, June 2020. https://www.fda.gov/media/71814/download

[2] FDA. Guidance for Industry. Product Recalls, Including Removals and Corrections. March 2020. Available at https://www.fda.gov/media/136987/download

[3] Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend. In general, Class I recalls may extend to the consumer or user level, Class II recalls may extend to the retail level, and Class III recalls may extend to the wholesale level.

[4] There are three recall classifications: Class I where products could cause serious health problems or death; Class II where products may cause a temporary or reversible adverse health problem or where the probability of a serious health problem is remote; Class III where the products are unlikely to cause any adverse health problems but violate FDA manufacturing or labeling laws.


FL00018081

consideration whether a recall will result in a product shortage or unavailability to patients in need of the therapy, and the resulting risk of causing patient harm. For Class I or II recalls, FDA will inspect the manufacturing facility to determine the root cause of the reason for the recall. For example, FDA may investigate for malicious tampering or accidental contamination (i.e. an unintentional error in the manufacturing, packaging or storage of a product, including mislabeling). FDA may also collect samples. Additionally, it should be noted that as a result of actual or alleged tampering with individual product unit(s) where there is no evidence of manufacturer or distributor responsibility, the FDA may recommend the action be designated as a Market Withdrawal since, although the situation may present a health hazard, there is no one identified as responsible for the violation.

***Supply Chain Entity Responsibility***

**A recall can be initiated either by a manufacturer or distributor or wholesaler-distributor**. In most cases, it is the manufacturer that bears the costs and responsibilities of the recall. In some cases where the manufacturer is out of business, in bankruptcy or is located in a foreign country (thus beyond FDA's jurisdiction), the US-based wholesaler-distributor may become the ultimate responsible party. The bottom line consequence to a wholesaler-distributor may be substantial since the net profit realized on a sale is a small fraction of the product's sale price or replacement cost. Consequently, we advise Safe Chain to ascertain if it has recall insurance coverage or if it has product contamination coverage. This may, but is often not, part of the firm's general liability policy.

As previously mentioned, recalls are considered the responsibility of the manufacturer. However, because of their position in the supply chain, wholesalers frequently conduct the actual recall. That is recalls are channeled through the wholesaler. If the product defect which led to the recall occurs at the wholesaler (e.g. flood), the wholesaler will play a greater role. Traditionally, the wholesaler's responsibility has been a traceability exercise where the wholesaler receives the recall notice from the manufacturer and conducts the recall.

It remains the responsibility of the manufacturer to notify the appropriate FDA Division Recall Coordinator (DRC) or Center contact as soon as a decision is made that a recall is appropriate and, if feasible, prior to the issuance of a notice to the public or written communications to customers. For the manufacturer to locate their recall coordinator, they need to check the following website: https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators. The manufacturer must provide all the requested information and work with the FDA to develop a recall strategy. The manufacturer must provide the notice of recall to its direct account consignees (e.g. wholesalers) together with appropriate instructions based on the recall level, strategy, etc. An example of such letter Safe Chain may receive is found at Exhibit 7-4 of FDA's Recall Procedures Manual https://www.fda.gov/media/71814/download. Instructions from the manufacturer to the wholesaler (i.e. Safe Chain) may be any or all of the following:

- Remove product from sale
- Cease distribution
- Sub-recall (if appropriate)

- Return or correct product

The manufacturer must notify both "ship to" and "bill to" customers of the recall so that: "Ship to" customers can retrieve the product from their location and "Bill to" customers, if responsible, can initiate the sub-recall. Safe Chain wholesalers may be either a “ship to” or a “bill to” customer. A sub-recall occurs when a consignee (e.g. wholesaler) further distributes a recalled product without changing the product. A sub-recall is an action taken by that consignee to notify its own accounts. If a consignee of the recalled product (e.g. wholesaler) refuses to initiate a sub-recall promptly, the FDA may take action to achieve a satisfactory sub-recall. Options for consideration include meetings between division management and top management of the recalling firm and/or sub-recalling firm, notification of consignees directly, reporting to State and local officials, recommendation for FDA requested or ordered recall, and initiation of administrative proceedings or enforcement actions.

***Recall to the Retail Level***

For recall actions going to levels beyond the wholesaler, Safe Chain would be responsible to contact all of its customers who have received the product including any customers or organizations that would not be on a mailing list used by the manufacturer and that you have supplied with the affected goods. If a manufacturer has voluntarily initiated a recall of any product(s), then it is responsible for promptly notifying each of its direct accounts (e.g. wholesalers). If the depth of the recall is beyond the direct accounts (e.g. to retail or even consumer level), then the direct accounts should be instructed by the recalling firm to contact sub-accounts that may have received the product. Sub-accounts, which further distributed the product, should continue the process. Common examples include:

- offshore pharmacies
- exporters supplied by the wholesaler
- clinical trials organizations
- retailers licensed to sell pharmacy-only medicines
- private hospitals
- paramedic organizations
- organizations that may include the affected goods in a new combination of goods (kits, OR trays)

Additional wholesaler responsibilities include quarantining stock on hand. The wholesaler compiles the customer lists. Additionally, the wholesaler receives recalled product and quarantines the stock received from the recall (from retailers). The wholesaler is responsible for issuance of the recall letter, ensuring that wholesale customers are notified of the recall, monitoring the progress of the recall and ensuring efficient recovery of recalled stock. Recalled products must be disposed of according to instructions outlined in the manufacturer’s recall notice. The wholesaler is also responsible for transferring quarantined stock back to the distributor or manufacturer. In most cases, recalled medications are returned to the wholesaler or manufacturer by the retail customers. In addition, any documentation required by the recall notice must be completed and submitted (e.g., manufacturer's inventory notification form). Safe Chain will be required to complete the Recall Response form in Exhibit 7-5 of FDA’s Regulatory Procedures Manual https://www.fda.gov/media/71814/download and indicate you are a wholesaler/distributer.

***Effectiveness Check Level***

The wholesaler may also be responsible for the effectiveness checks for a recall. The purpose of a firm's effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. See Exhibit 7-1 Model Effectiveness Check Letter https://www.fda.gov/media/71814/download.

***Recall Termination***

A recall will be terminated when the FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate FDA division office to the recalling firm.

***Conclusions and Recommendations***

Wholesaler-distributors are subject to many laws related to product liability, which can vary from state to state. It is important to understand that continuing to distribute a recalled product or one that the wholesaler knows may be defective can and has resulted in product liability claims. We recommend that Safe Chain obtain recall insurance coverage or product contamination coverage if it does not already have this. It is imperative to cease all distribution of the product and quarantine it. Report any customer complaints to the manufacturer immediately. If the manufacturer fails to act properly and promptly notify the FDA or complete the necessary paperwork and the situation is likely to warrant a recall or result in patient harm, then the duty falls upon the wholesaler. The wholesaler then has a duty to report to the situation to the FDA and initiate the recall. We have pharmaceutical industry experience with product recalls, traceability plans, and effectiveness checks. To respond with expertise and decisiveness development of recall SOPs and/or a model recall plan for Safe Chain are recommended. Please do not hesitate to engage Frier Levitt's Regulatory Practice attorneys further in this or future FDA related matters.